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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,782	12/16/2005	Andreas Lendlein	Q116791	2455
23373 7590 11/22/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			EXAMINER AZPURU, CARLOS A	
			ART UNIT 1617	PAPER NUMBER
			NOTIFICATION DATE 11/22/2010	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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USPTO@SUGHRUE.COM

<b>Office Action Summary</b>	<b>Application No.</b> 10/520,782	<b>Applicant(s)</b> LENDLEIN ET AL.	
	<b>Examiner</b> Carlos A. Azpuru	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-16,18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-16, 18 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt is acknowledged of the amendment filed 09/24/2010.

The objection to claims 2,6, 13 and 16 is withdrawn in view of applicant's amendment and cancellation of claims.

The following rejection is maintained and adjusted to applicant's amendment in this action:

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 1, 3, 5-16, 18 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Langer et al (US Patent No. 6,388,043).

Langer et al teaches a shape memory polymer (SMP) which can hold more than one shape memory, and that these compositions comprise at least one hard segment and at least one soft segment (Abstract; cols. 2-4; col2. 12-15). The reference goes on to teach that the SMP's can be used in the manufacture of vascular stents, medical guide wires and other medical uses (col. 1), The SMP's are characterized as phase segregated linear block co-polymers which have both a hard and soft segment as described above (cols. 1-2) The ability to hold more than one shape memory is disclosed at col.2, lines 51-56. The polymers may be biodegradable (col. 5, lines 6-22). These polymers can be a single or polymer blends. The polymers themselves can be linear, branched, thermoplastic elastomers with side chains or any kind of dendritic structural elements. Stimuli causing shape change can be temperature, ionic change, pH, light, electric field, magnetic field, or ultrasound. Thermoplastic shape memory materials can be shaped (e.g molded) to a desired shape above the T of the hard segment(s) and cooled to a temperature below the shape recovering temperature, where the polymer may undergo mechanical deformation, and strains generated in the polymer. The original shape of the deformed polymers can be recovered by heating them to a temperature higher than their shape recovering temperature. Above this temperature, the strains in the polymer are relieved, allowing the polymer to return to its

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original shape (see col. 5, lines 23-40; col. 9, lines 25-36; col. 10, lines 59 to col. 11, line 27). Langer et al further teaches the inclusion of bioactive materials, such as inorganic and organic compounds proteins, peptides, polysaccharides such as sugars, lipids, and nucleic acid molecules (cols 15-16). It further suggested that the composition can be used in biomedical applications such as, sutures, orthodontic materials, bone screws, nails, plates, Meshes, prosthetics, pumps, catheters, tubes, films, orthopedic braces, splints tape, contact lenses, drug delivery devices, implants, thermal indicators and tissue scaffolds for tissue engineering (col. 16, lines 21-30). Polymers for us in SMP's are listed at cols. 6-9. While Langer et al does not set out that "the shape memory effect is used to vary the drug release rate", the shape memory drug delivery system of Langer et al would inherently have said property. Additionally, the use of the shape memory drug delivery composition as claimed to vary the drug release rate may also be viewed as an intended use of the instantly claimed composition. The instant claims are anticipated by Langer et al

However, if the instant claims are not anticipated by Langer et al because the claims now set out that "the shape memory effect is used to vary the drug release rate", Langer et al clearly sets out a shaped memory drug delivery release system. Those of ordinary skill would have expected the shape memory to deliver the same therapeutic effect. Further, if the change in drug release rate is a heretofore unknown property of such drug delivery systems, the same shape memory drug delivery system, used for the same therapeutic effect, in the same tissue, would be expected to have the same drug delivery device properties, including the change in drug release rate due to the

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shape memory. As such, the instant invention would have been obvious to one of ordinary skill at the time of invention given the teachings of Langer et al.

### ***Response to Arguments***

Applicant's arguments filed 09/24/2010 have been fully considered but they are not persuasive.

Applicant argues that the reference does not teach or disclose ". the shape memory effect is used to vary the drug release rate". However, Langer et al discloses the same shape memory composition and the same therapeutic effect. As such, :Langer et al either anticipates or makes obvious the instant claims in that the same polymers used for the same therapeutic purpose would be expected to have the same characteristics.

The following is a new rejection of the claims based on applicant's amendment:

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 3, 5-16, 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant has amended the claims to read on a shaped memory drug delivery system which ".the shape memory effect is used to vary the drug release rate". No support is found in the original specification for this limitation. The original specification seems to indicate that diffusion and degradation define the drug release. Clarification is requested,

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi can be reached on (571) 272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1617

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